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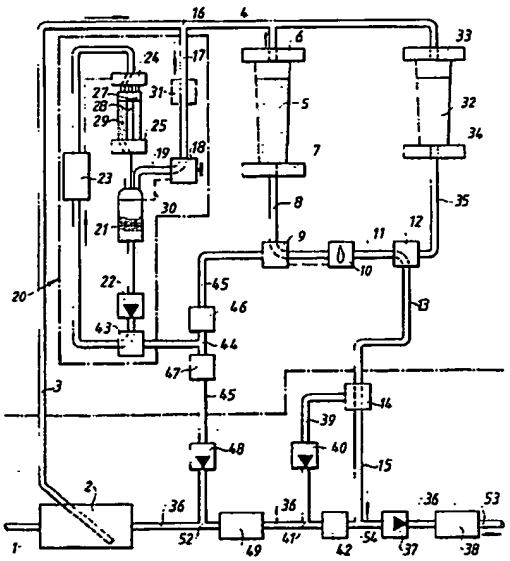
(54) **System for preparation of a fluid intended for medical use.**

(57) System for preparation of a fluid intended for medical use, for example dialysis fluid or replacement fluid for heamofiltration or a concentrate for preparation for such fluids, including a source (1, 2) of pure water and at least one cartridge or another vessel (27-29) containing a powder which is to be dissolved in the said water for preparation of the desired fluid.

The system according to the invention is characterized by means (3, 16, 17, 18, 19) for conducting the water to a mixing vessel (21) and said cartridge or cartridges (27-29) and means (22) for recirculation of the water or partially prepared fluid through said cartridge or one of said cartridges until an appropriate concentration from the complete or partial dissolving of the powder is obtained.

Fig.1



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TECHNICAL FIELD

The present invention relates to a system for preparation of a fluid intended for medical use, for example, dialysis fluid or replacement fluid for haemofiltration or a concentrate for preparation of such fluids, including a source of pure water and at least one cartridge or another vessel containing a powder which is to be dissolved in the said water for preparation of the desired fluid.

BACKGROUND ART

Previous system available for similar purposes normally start from one or more liquid based concentrates. For example US-patent 4 158 034, describes how a concentrate in liquid form is mixed with water for preparation of a dialysis fluid. In European patent EP-B1-O 022 922 and US-patent 4 783 273 there is described how two liquid-based concentrates are mixed with water to achieve a fluid intended for medical use, for example dialysis fluid. More recently systems have been introduced which instead make use of one or more concentrates in powder form. As an example. US-patent 4 784 495 describes how one or more such powder-based concentrates can be used with or without addition of a liquid-based concentrate.

Should one want to use a powder-based concentrate which is hard to dissolve, then it can be difficult to achieve an adequately fast dissolving when using the system according to the above-mentioned US-patent 4 784 495. Furthermore, the system according to said patent can become relatively complicated if it is desired to add several different individual pre-packed powder-based concentrates.

DISCLOSURE OF THE INVENTION

The above-mentioned problems are solved with the help from the present invention which thus relates to a system for preparation of a fluid intended for medical use, for example dialysis fluid or replacement fluid for haemofiltration or a concentrate for preparation of such fluids, including a source of pure water and at least one cartridge containing a powder which is to be dissolved in the said water for preparation of the desired fluid.

The system according to the invention is primarily characterized by means for conducting the water to a mixing vessel and by a recirculation circuit including this mixing vessel and said cartridge or cartridges or means for connecting these and means for recirculation of the water or partially prepared fluid through said cartridge or one of said cartridges until an appropriate concentration is obtained by dissolving the powder entirely or partly. By means of this recirculation even a relatively difficult to dissolve powder-based concentrate can be dissolved. At the same time a liquid-based concentrate can be prepared in the mixing vessel from one or more powder-based concentrates which, after preparation, can be conveyed to conventional dialysis machines which otherwise normally receive such liquid-based concentrates from one or more containers.

Preferably, according to the invention, a plurality of parallelly-connected cartridges, which are arranged to be able to be connected one by one to the recirculation circuit, are used. In this way precisely the right amount of concentrate for the patient can be taken from each cartridge. In other words an individual dosage can be obtained.

Not all substances are suitable for use in a powder form. Therefore a vessel for a liquid-based concentrate intended to be included in a finally prepared fluid can be connected in parallel with said cartridge or cartridges.

Preferably said means for recirculating the water or partially prepared fluid consists of a recirculation pump of a type such that it is suitable for metering the fluid prepared in the mixing vessel.

To control the condition of the mixture, a conductivity measuring device is appropriately arranged in the recirculation circuit, said device being arranged so as to stop the recirculation through the connected cartridge when the desired conductivity is obtained. Other suitable means for measuring the concentration, such as a pH-meter or an ion-selective meter, can, of course, be used as well. The same substitution can also be made for the conductivity meters mentioned in the rest of this description.

Should a plurality of parallelly-connected cartridges be included in the system according to the invention, then these are suitably controlled by a valve unit which is arranged to connect said cartridges and/or vessels one by one to the recirculation circuit.

Not all of the cartridges need to be included in the recirculation circuit. Instead, means can be provided for conducting water from said water source directly to a cartridge connected in parallel to the other cartridges for dissolving the substance therein which is intended to form a part of the finally prepared fluid. The system shall in such a case include a conduit for the transport of the water with the dissolved substance to a place of consumption, whereby means can be arranged to add during this transport the solution partially prepared in the recirculation circuit.

In order to control the condition of the mixture in such a combined system, a conductivity measuring device can be arranged in the outlet conduit from the said parallelely-connected cartridges. With

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this conductivity meter the conductivity in the prepared fluid can be measured before and/or after the addition of said partial solution. If measurements are made before and after the addition, then a differential conductivity meter may be used. This is particularly suitable if only a small change in conductivity occurs due to the addition.

If a conductivity meter is used which measures the conductivity only after the addition of the said partial solution, then the latter should be added with the help of an accurately metering dosage pump. In that way can theoretically be calculated which portion of the conductivity is due to the supplied partial solution, and which proportion is due to the dissolved concentrate from said parallelly-connected cartridge.

To control the quantity of water supplied to said mixing vessel a valve is suitably arranged in the transport conduit between the water source and this vessel, the valve being arranged to be closed when the mixing vessel contains a predetermined quantity of water or partially prepared fluid. The mixing vessel can for example comprise a level indicator which controls the valve arranged in the transport conduit.

Should a liquid-based or a very easily dissolvable powder concentrate be supplied to the mixing vessel , then this can occur with the help of direct conduit for conducting water from said water source straight to one of said cartridges and/or vessel for flushing therefrom a predetermined quantity of liquid and/or powder directly to the mixing vessel.

Said cartridge, cartridges and/or vessels should appropriately contain from the outset an excess of powder concentrate, so that the circulation in the recirculation circuit can be interrupted before the cartridge and/or vessel connected to the recirculation circuit is totally emptied. Hereby it is assured that the desired concentration of the added substance can always be obtained.

A preferred embodiment of the system according to the invention is characterized by means for conducting water from said water source directly to a further cartridge parallel connected to the other cartridges for dissolving a substance therein, this substance being intended to be included in the finally prepared fluid, and by a conduit conducting the water with dissolved substance to a place of consumption, at which means are arranged to measure the concentration of said substance or a value corresponding to this concentration before and after the mixing points in a main line, which, with the help of the other cartridges and/or vessels, is arranged to conduct a partially prepared liquid to a place of consumption after the mixing in of a dissolved substance from the last-mentioned cartridge.

The invention also includes a modification of the above-described system, characterized in that said cartridge or other vessel is arranged to serve as said mixing vessel by containing from the outset the desired quantity of salt. This salt can easily be dissolved in the recirculation circuit included in the system according to the invention. When it is fully dissolved, which can be checked by means of, for example, a conductivity meter, the prepared solution can be conveyed to, for example, a dialysis machine instead of conventionally prepared liquid-based concentrate.

Certain advantages can be obtained if the mixing vessel in addition to the said salt also contains a smaller quantity of liquid, preferably water, of such quantity that a concentrated liquid or mud of said liquid and the powder-based salt is formed. Such a concentrated liquid can more easily be checked that it is lump-free compared with a more or less compacted powder in dry form.

The salt in the form of dry powder or concentrated liquid in the mixing vessel is more easily dissolved when the recirculation circuit includes a heating device.

Particularly when the mixing vessel contains a concentrated liquid, besides the said salt, it can also contain an acid in liquid form. Many medical solutions, for example dialysis fluid, should actually contain such an acid and this can already be added before the preparation of the final solution. Alternatively the acid can be added by means of the recirculation circuit being connected to a branch conduit with a dosage-pump, which is arranged to pump an acid in liquid-form from its storage vessel to the recirculation circuit. From a medical point of view it can be appropriate for the recirculation circuit to include a sterile filter, which is preferably arranged in the circulation direction just before the mixing vessel.

According to a preferred embodiment of the invention the mixing vessel is connected to the recirculation circuit with the help of quick-released connectors so thus it can easily be uncoupled and connected instead to, for example, a dialysis machine instead of the traditionally employed dialysis concentrate container.

The mixing vessel can appropriately consist of a flexible plastic bag. By the use of such a bag a check can be made to see if the salt is lump-free, whether it is in dry form or in the form of a liquid concentrate.

BRIEF DESCRIPTION OF THE DRAWINGS

Figures 1-3 show in the form of a block diagram a preferred embodiment of the system according to the invention in its three different connectable positions.

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Fig. 4 shows a diagram of the measured conductivity in the above-described recirculation circuit with the supply of three different concentrates.

Figures 5a and 5b finally show a modified embodiment of the system according to the invention.

PREFERRED EMBODIMENTS OF THE SYSTEM ACCORDING TO THE INVENTION

Figures 1-3 show by way of a block diagram a preferred embodiment of the system according to the invention in its three different connectable positions. Figure 1 is hereby intended to show how a recirculation circuit 20, respectively a separate powder cartridge 5, is filled with water. This water is taken from an inlet 1 via a heating vessel 2 through conduits 3 and 4 to said powder cartridge 5, which is located between two connection pieces 6 and 7. When the cartridge 5 is filled, the water is further passed as showed in figure 1 through a conduit 8 and a valve 9 to a detector 10, which detects the water and/or concentrate dissolved therein. This can possibly occur with a certain time delay so that the fluid will have time to fill the subsequent conduit 11, valve 12, conduit 13, valve 14 and conduit 15.

At the same time, water is conveyed from a branch point 16 through a conduit 17, a valve 18 and a conduit 19 to a recirculation circuit, which in its entirety is denoted by 20. This circuit includes a mixing vessel 21, a recirculation pump 22, a concentration measuring device 23, for example a conductivity meter, and connected between two valve units 24 and 25 a number of cartridges or other vessels 27, 28 and 29 for one or more powder concentrates and possibly some liquid-based concentrate. When a sufficient quantity fluid is supplied to the mixing vessel 21, the valve 18 is closed. This can occur with the help of a level indicator schematically shown by the dashed line 30. Thereafter, the recirculation pump 20 is started with the valve units 24 and 25 so positioned that the water is passed through one of the vessels or cartridges 27-29.

In figure 1 it is the vessel 29 which is connected. When the desired conductivity is obtained, which is controlled with the help of the meter 23, the next cartridge 28 is instead connected, and then finally cartridge 27. Should the prepared fluid in the mixing vessel 21 include another liquid-based or easily dissolvable concentrate, then the dissolving can occur during the filling of the mixing vessel 21 with the vessel containing this concentrate being connected to the conduit 17. Such a vessel 31 is indicated in a block-form with the help of dashed lines.

When the recirculation circuit 20 is filled, the valve 18 is closed as showed in figure 2. In the same way, valve 9 is actuated when the vessel 5 is filled. This position is also showed in figure 2. At the same time, the valve 12 is switched from the position shown in figure 1 to that in figure 2, so that water from the conduit 4 can pass to another vessel or powder cartridge 32 located between two connection pieces 33 and 34. When this cartridge 32 has been filled the water with dissolved concentrate therein is conducted through the conduit 35, valve 12, conduit 13, valve 14 and conduit 15 to a main line or conduit 36 which includes a pump 37 and a detector 38, for example a conductivity measuring device. This detector controls the valve 14 so that it is switched to the position shown in figure 3. The fluid from the vessel 32 is now conveyed instead from the valve 14 via a conduit 39 with a dosage pump 40 to the main line 36 to a point 41 upstream of a restrictor 42. This restrictor 42, together with the pump 37 and a gastrap not shown arranged further downstream, is used for de-gasing the prepared fluid.

With the switching of the valve 14 to the position shown in figure 3, the described system is ready for dialysis. An inlet valve 43 in the recirculation circuit 20 is thus actuated so the pump 22 can pump prepared fluid from the mixing vessel 21 to a mixing point 44, to which concentrate from the vessel 5 is conducted via the valve 9 and the conduit 45. The appropriate concentration of the dissolved substance is measured in this conduit upstream and downstream of the mixing point 44. This can be achieved, for example, by means of a differential conductivity meter, whose measuring points are denoted by 46 and 47 respectively. The prepared solution can then be conducted further through the conduit 45 with the help of a pump 48, which preferably consists of an accurately metering dosage pump. With the help of this the prepared solution is conducted to the main line 36, in which the concentration is once more checked by means of a meter 49, for example another conductivity measuring device. This meter 49 then controls the pump 48, as showed by the dashed line 50 in figure 3. Additional concentrate is then added to the prepared solution at the mixing point 41 by means of a pump 40 controlled by the measuring device 38 as indicated by the dashed line 51. By means of this measuring device 38, which preferably consists of a conductivity meter, the final concentration of the prepared solution obtained from the system according to the invention is regulated.

Finally, figure 4 shows a diagram of how the conductivity in the recirculation circuit 20 varies. Here it is assumed that the meter 23 consists of a conductivity measuring device and that the vessels 27, 28 and 29 contain three different salts. Thus,

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between time t0 and t1 one of these vessels is connected until the conductivity value c1 is obtained. Thereafter, the next vessel is connected until the conductivity value c2 is reached. Then the last vessel is connected which remains connected until the conductivity obtains the desired value c3. At this point the valve 43 is switched over so that the ready-prepared solution can be conducted to the mixing point 44. At this mixing point concentrate from the vessel 5 is added. The thus obtained mixture is then led to a mixing point 52 in the main line 36 where it is mixed with water from the heating vessel 2. At the next mixing point 41, concentrate from the vessel 32 is then added. After a final check in the measuring device 38, the ready prepared solution can then be conducted to its place of consumption, as symbolized by an arrow 53.

Finally figures 5a and 5a show a modification of the system according to the invention. Since this modification corresponds in principal with the above-described system, the same reference numerals have been used, but with the addition of a. In this system, pure water enters via an inlet 1a and is pumped with the help of a pump 22a through a recirculation circuit 20a which further includes a heater 61a, a control device, for example a conductivity meter 23a, a sterile filter 58a and a mixing vessel 21a. With this arrangement the mixing vessel 21a should, from the outset, contain the desired quantity salt. This can possibly be in dry form, or as a concentrated liquid obtained by adding a small quantity of liquid thereto. Such a concentrated liquid can be complemented by possibly necessary acid in liquid form. This acid may however also be added in different forms. Certain acids can, for example, be obtained in dry powderform.

Acid in liquid form can be added via a branch conduit 55a with a dosage pump 56a, as shown in figure 5b. The acid can thus be taken from a vessel 57a and introduced into the recirculation circuit via a valve 60a. The mixing vessel 21a is preferably connected to the recirculation circuit 20a via quick-release connectors 59a, so that it can easily be uncoupled and connected instead to, for example, a dialysis machine instead of the traditionally employed dialysis concentrate container.

EXAMPLE

Using the system described in figure 5a and 5b for preparation of a dialysis liquid solution, the following mixture was presence in the vessel 21a:
NaCl ≈ 1 050 gram
KCl ≈ 13 gram
CaCl ≈ 45 gram
MgCl ≈ 18 gram.

All of these salts were present in the form of a powder. To this was added approximately 2 dl of fluid, comprising essentially water, but to which approximately 32 g of acetic acid had been added. In this case a flexible plastic bag was used for the mixing vessel 21a. Thereby it was possible to check that a lump-free concentrated liquid was obtained. It should be appreciated that a somewhat smaller quantity of liquid can be used. Alternatively an excess of liquid can be added, but for practical reasons it is advisable to keep the weight of the mixing vessel 21 and its contents down.

Naturally the invention is not limited simply to the embodiment described above, but may be varied within the scope of the following claims. For example, the parts included in the system may be varied within wide limits with regard to their form as well as their function. For example the containers 27-29 and 31 can be combined together, for example in the form of a flexible bag or similar with a desired number of compartments.

Claims

1. System for preparation of a fluid intended for medical use, for example dialysis fluid or replacement fluid for heamofiltration or a concentrate for preparation of such fluids, including a source (1, 2) of pure water and at least one cartridge or another vessel (27-29) containing a powder which is to be dissolved in the said water for preparation of the desired fluid, **characterized** by means (3, 16, 17, 18, 19) for conducting the water to a mixing vessel (21) and by a recirculation circuit (20) including this mixing vessel (21) and said cartridge or cartridges (27-29) or means (24, 25) for connecting these and means (22) for recirculation of the water or partially prepared fluid through said cartridge or one of said cartridges (27-29) until an appropriate concentration is obtained from the complete or partial dissolving of the powder.

2. System according to claim 1, **characterized** by a plurality of parallelly-connected cartridges (27-29) which are arranged to be able to be connected one by one to the recirculation circuit (20).

3. System according to claim 1 or 2, **characterized** by a vessel in (31 or one of 27-29) connected in parallel with said cartridge or cartridges (27-29), said vessel containing of a liquid-based concentrate intended to be included in the finally prepared fluid.

4. System according to any of the previous

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claims, **characterized** in that the said means for recirculating the water or partially prepared fluid consists of a recirculation pump (22) of a type such that it is suitable for metering the fluid prepared in the mixing vessel (21).

5. System according to any of the previous claims, **characterized** by a conductivity measuring device (23) within the recirculation circuit (20), which is arranged so as to stop the recirculation through the connected cartridge (27-29) when the desired conductivity is obtained.

6. System according to any one of claims 2-5, **characterized** by a valve unit, (24, 25) which is arranged to connect said cartridges and/or vessels (27-29) one by one to the recirculation circuit (20).

7. System according to any of the previous claims, **characterized** by means (3, 4) for conducting water from said water source (1, 2) directly to a cartridge or another vessel (5) connected in parallel to the other cartridges (27-29) for dissolving the substance therein which is intended to form a part of the finally prepared fluid, and by a conduit (8, 45, 36) for transporting the water with dissolved substance to a place of consumption (53), means (22, 43) being arranged to add the partial solution prepared in the recirculation circuit (20) during this transportation.

8. System according to claim 7, **characterized** by a conductivity measuring device (46 and/or 47) arranged in a transport conduit (45) from the said parallelly-connected cartridge (5) arranged to measure the conductivity in the prepared fluid before and/or after the addition of said partial solution.

9. System according to claim 8, **characterized** in that the conductivity meter (47) is arranged after the addition of said partial solution, whereby the latter is added with the help of an accurately metering dosage pump (22).

10. System according to any of the previous claims, **characterized** by a valve (18) arranged in the transport conduit (3, 17) between the water source (1, 2) and the mixing vessel (21), the valve being arranged to be closed when the mixing vessel (21) contains a predetermined quantity of water or partially prepared fluid.

11. System according to any of the previous claims, **characterized** by a direct conduit (3, 17) for conducting water from said water source (1, 2) straight to one of said cartridges and/or vessel (31 or one of 27-29) for flushing therefrom a predetermined quantity of liquid and/or powder directly to the mixing vessel (21).

12. System according to any of claims 1-10, **characterized** in that said cartridge, cartridges and/or vessels (27-29) contain an excess of powder concentrate, so that the circulation in the recirculation circuit can be interrupted before the cartridge and/or vessel connected to the recirculation circuit is totally emptied.

13. System according to claim 7. **characterized** by means (3, 4) conducting water from said water source (1, 2) directly to another cartridge (32) parallelly connected to the other cartridges (5, 27-29) for dissolving a substance therein, this substance being intended to be included in the finally prepared fluid, and by a conduit (35, 13, 15 or 39, 36) for conducting the water with dissolved substance to a place of consumption (53), means (49, 38) being arranged to measure the concentration of said substance or a value corresponding to this concentration before and after a mixing point (54 or 41) in the main line (36), which is arranged to transport one with the help of the other cartridges and/or vessels (27-29,31,5) partly prepared liquid to the place of consumption (53).

14. Modification of the system according to any of the previous claims, **characterized** in that said cartridge or other vessel is arranged to serve as the mixing vessel (21a) by containing from the outset desired quantity of salt.

15. System according to claim 14, **characterized** in that the mixing vessel also contains a small quantity of a liquid, preferably water, in such a quantity that a concentrated liquid of said liquid and the powder-based salt is formed.

16. System according to either of claims 14 and 15, **characterized** in that the recirculation circuit (20a) includes a heating device (54a).

17. System according to any of the claims 14-16, **characterized** in that the mixing vessel (21a) contains a liquid acid as well as the said salt.

18. System according to any of the claims 14-16, **characterized** in that the recirculation circuit (20a) is connected to a branch conduit (54a)

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with a dosage pump (56a) which is arranged to pump an acid in liquid form from a storage vessel (57a) to the recirculation circuit.

19. System according to any of the claims 14-18, **characterized** in that the recirculation circuit (20a) includes a sterile filter (58a) which is preferably arranged in the circulation direction just before the mixing vessel (21a).

20. System according to any of the claims 14-19, **characterized** in that the mixing vessel (21a) is connected to the recirculation circuit with the help of quick-release connectors (59a) so that it can easily be uncoupled and connected instead to, for example, a dialysis machine instead of the traditionally employed dialysis concentrate container.

21. System according to any of the claims 14-20, **characterized** in that the mixing vessel (21a) consists of a flexible plastic bag.

22. System according to any of the claims 14-20, **characterized** in that the mixing vessel (21a) for preparation of a dialysis fluid contains an amount in the magnitude 1 kg of powder mixture of suitable, for example conventional, composition to which an amount in the magnitude of 2 dl of a liquid is added for preparation of a lump-free concentrated liquid or slush, which preferably contains the necessary quantity of acid for the dialysis fluid.

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Fig.1

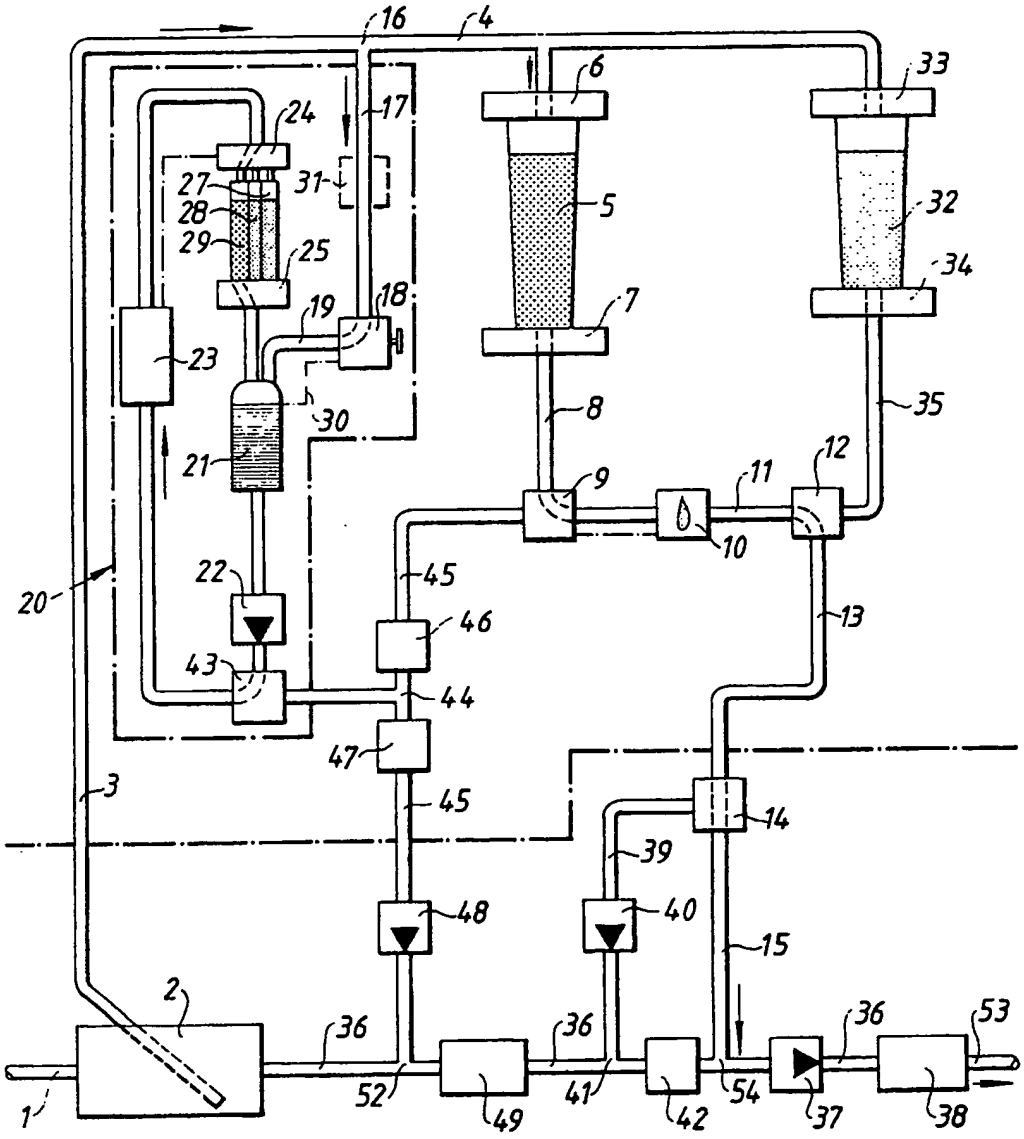

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Fig.2

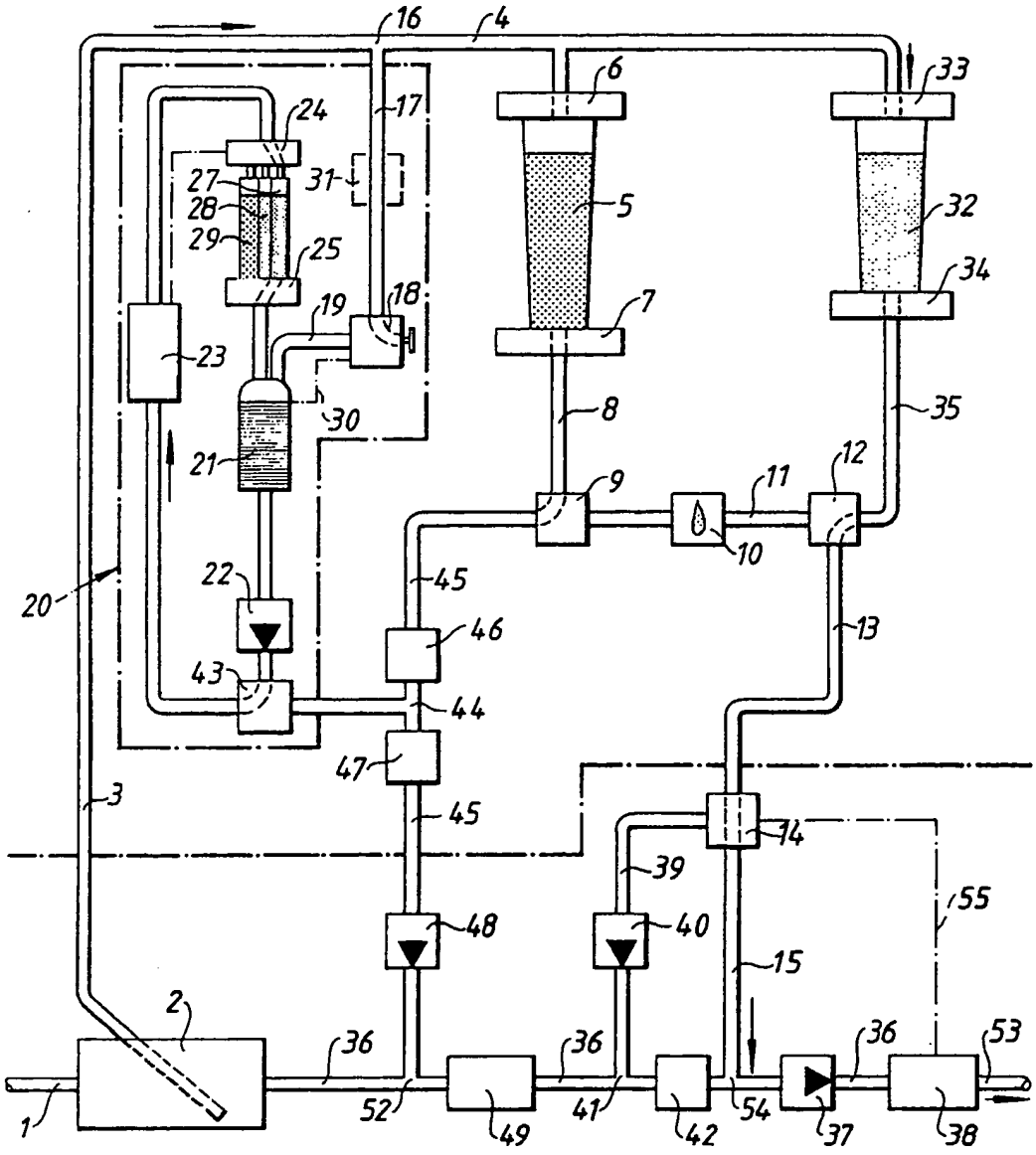

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Fig.3

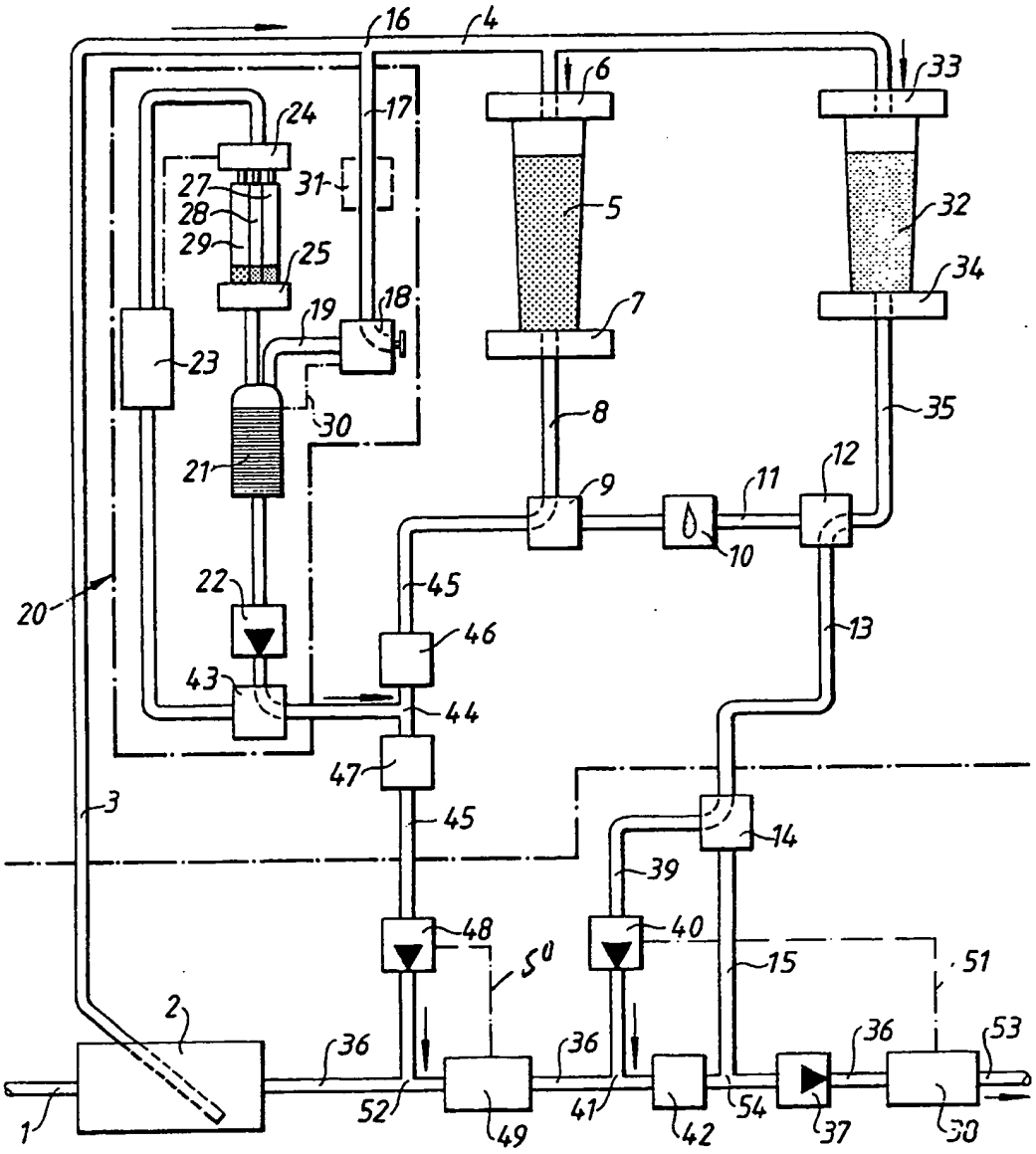

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Fig.4

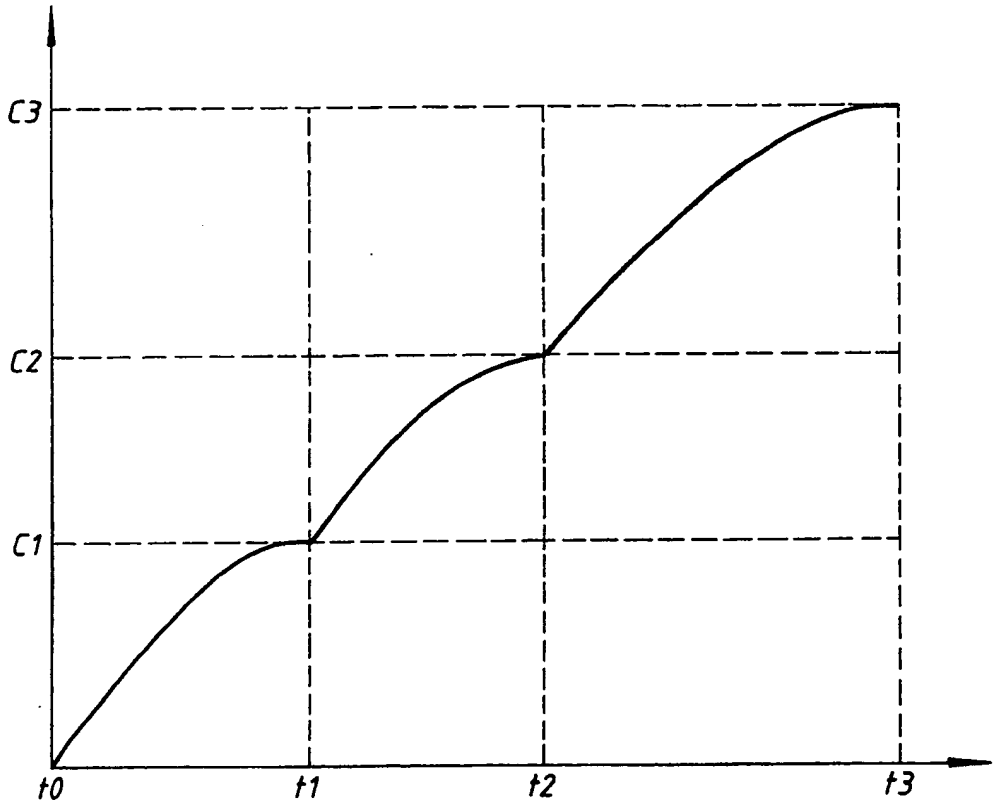

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Fig.5a

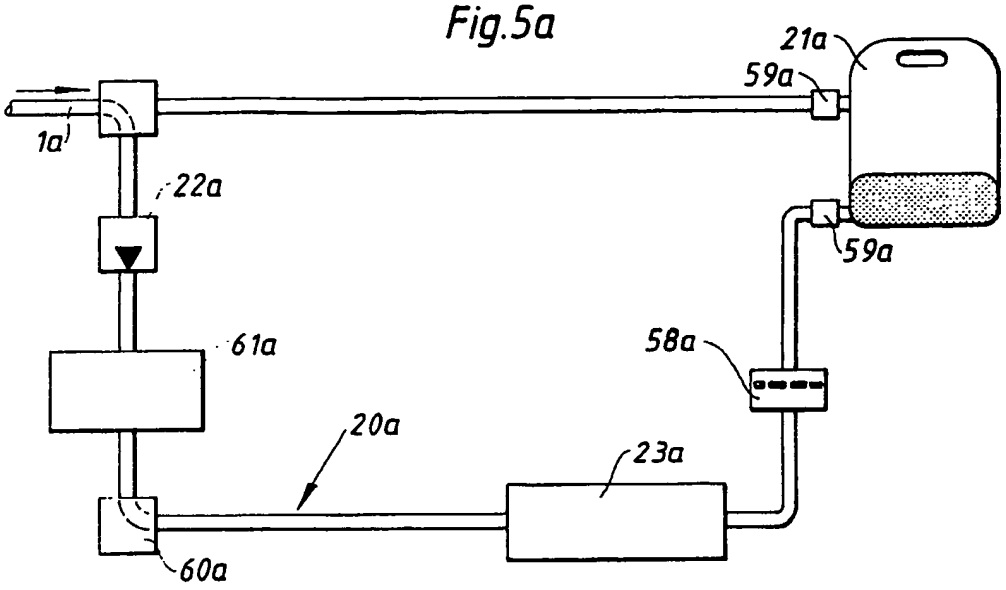
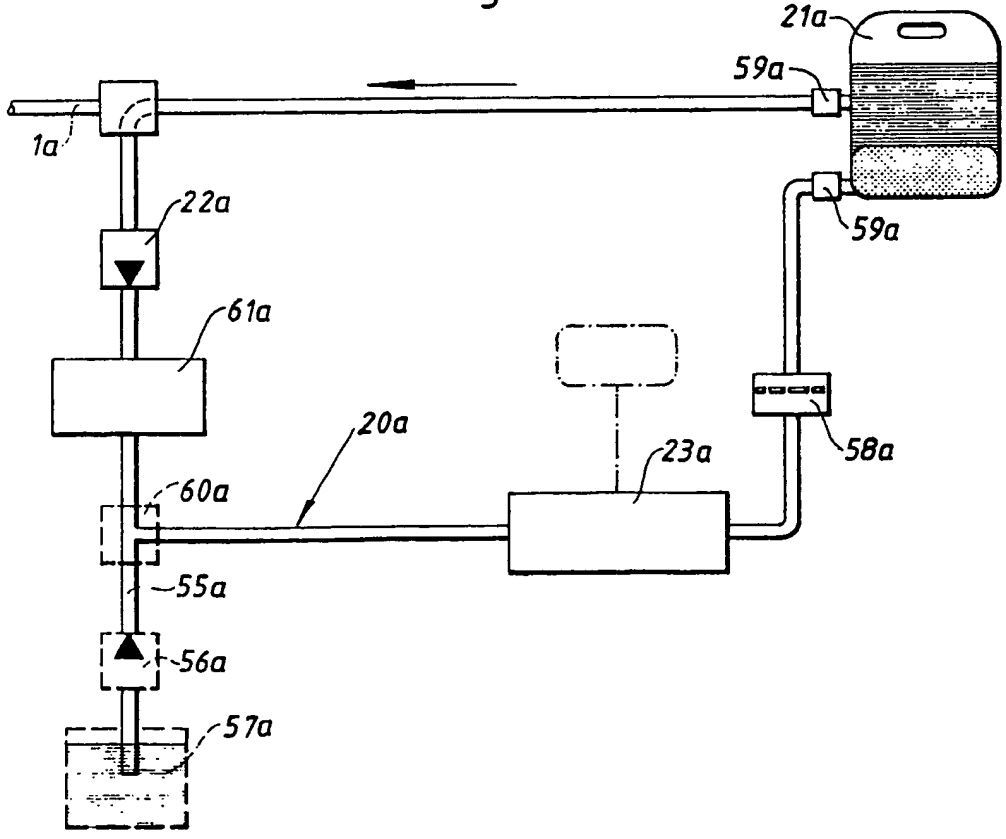


Fig.5b



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European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 91 10 0559

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
A	FR-A-1 333 222 (DELBERGUE) * the whole document *	1	B 01 F 5/10 A 61 M 1/16
A,D	EP-A-0 278 100 (GAMBRO) * TITLE * * figure 1 & US-A-4 784 495 (GAMBRO) *	1	
A	US-A-4 848 916 (MEAD) * abstract; figures 1,3 *	1	
A	DE-A-2 924 406 (SALVIA REGEL) * page 5, line 5 - line 12 *	4	
A	US-A-4 082 667 (SEILER) * column 2, line 15 - line 22; figure 1 *	5	

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

B 01 F
A 61 M

The present search report has been drawn up for all claims

Place of search	Date of completion of search	Examiner
The Hague	10 June 91	PAPONE F.

CATEGORY OF CITED DOCUMENTS

X: particularly relevant if taken alone
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